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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,622	09/11/2000	Henrik Sune Andersen	0776/1H462-US1	5060

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Joseph R. Robinson
Darby & Darby
805 Third Avenue
New York, NY 10022

EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/659,622	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 19, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-18, 20-23 and 29-31 is/are rejected.
- 7) ☒ Claim(s) 26-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-22-03</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of Case

1. Unless specifically repeated hereinunder, all previous rejections have been withdrawn.

2. The obviousness-type double patenting rejection over U.S.P. 6,262,044 has been withdrawn for the reasons argued in Applicant's response.

The examiner further notes that the claims of that patent, as well as those of U.S.P. 6,410,586, are also distinguished from the instant claims insofar as the latter require selecting particular compounds which optimize PTPase inhibition. See the discussion of pages 52-56 of the instant specification, for example. Additionally, the examiner notes that the conflicting claims require the treatment of various disease states, but not necessarily inhibition of PTPase activity. Conversely, instant claim 30 requires the inhibition of PTPase activity, but not necessarily the treatment of the claimed disease states.

3. This action is NON-FINAL.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 16-18, 20-23 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regents of the U. of Cal. v. Eli Lilly & Co., 119 F.3d 1159, 1568 (Fed. Cir. 1997), holds that:

[i]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

The recent case U. of Rochester v. G.D. Searle & Co., Inc., 249 F.2d 216, 225 (W.D.N.Y. 2003), clarifies that the holding of Lilly is not limited to claims directed to DNA or nucleic acid sequences.

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The facts of the Rochester case are viewed as being applicable to those of the instant case. In Rochester, a method for selectively inhibiting prostaglandin synthase activity was recited and an assay for determining whether specified candidate inhibitors would be useful was described by the specification, but the claims were not limited to specific inhibitor species. The court observed at page 229:

Even if the inventors were reasonably certain that the necessary compound existed and eventually could be found, there is no showing in the patent that they knew that to be a fact. In short, without possession, or at least knowledge, of such a compound, or of a method certain to yield such a compound, the inventors could not have possessed the claimed invention, *i.e.* a method of treatment using the compound.

The court also noted at page 223:

By its own terms, then, the '850 patent describes methods for 'screening' and 'evaluat[ing]' the effect of various compounds on PGHS-1 and -2 activity. It also describes some of the steps to be taken once a suitable compound has been identified, in order to make it possible to practice the claimed invention.

What the '850 patent does *not* do, however, is provide the necessary link between those two steps: actually finding a compound that works. It provides precious little guidance in the way of selecting a particular compound, or even of narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation.

And again at page 235:

In short, although the '850 patent describes an assay for determining whether a given compound possesses certain desired characteristics, and identifies some broad categories of compounds that *might* work, these descriptions, without more precise guidelines, amount to little more than a 'starting point, a direction for further research.' Genentech, 108 F.3d at 1366. See *a/so Calgene*, 188 F.3d at 1374 ('the teachings set forth in the specification provide no more than a 'plan' or 'invitation' for those of skill in the art to

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experiment practicing [the claimed invention]; they do not provide sufficient guidance or specificity as to how to execute that plan').

In the instant case, Applicant recites methods for inhibiting PTPases and an assay for determining whether specified candidate inhibitors are suitable as described by the specification, but the claims are not limited to specific inhibitor species. Claims 1-13, 16-18, 20-23 and 29-31 instead recite species characterized incompletely by functionality ("interactions" with various enzyme sites) and nominal partial structure (the various specifically recited heterocyclic moieties). As in Rochester, the teachings set forth in the specification represent no more than a "plan" or "invitation" to experiment with various partially characterized compounds which might be verified as PTPase inhibitors, without any reasonable expectation of success.

Applicant will note that claims 26-28 are not rejected on this basis. See the "Allowable Subject Matter" section hereinbelow.

Enablement Rejection

Claims 1-13, 16-18, 20-23 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of PTPases by inhibitors falling within the scope of the generic structural formula recited in claim 28, does not reasonably provide enablement for the use of inhibitors incompletely recited by functional characteristics coupled with nominal partial structure. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to inhibiting PTPases.

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The relative skill of those in the art is generally that of a PHD candidate or PHD.

The unpredictability of enzyme inhibition is well understood, due to the very precise fit necessary between an inhibitor and the corresponding site on an enzyme.

2. The breadth of the claims

The claims are very broad and inclusive of inhibitors characterized incompletely by functionality and nominal partial structure.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining which particular inhibitions, known or to be discovered, can reasonably be expected, *a priori*, to inhibit PTPases, beyond the limited scope of compounds having the particular generic formula set forth in claim 28.

The instant working examples (pages 299-307 of the instant specification) run activity assays on a few select inhibitors, all within the scope of the generic formula set forth in claim 28.

4. The quantity of experimentation necessary

Applicant fails to provide guidance and information sufficient to allow the skilled artisan to ascertain which specific inhibitors, known or to be discovered, can be used to inhibit PTPases, without resorting to undue experimentation. The skilled artisan would expect the interactions of a particular inhibitor and enzyme to be very specific and highly unpredictable, with no *a priori* expectation of success for using specific inhibitors beyond the scope of the generic formula set forth in claim 28. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as it is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Allowable Subject Matter

Claims 26-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Instant claim 28 recites compounds having a specified generic formulae, and thus provides an adequate written description as required by the Eli Lilly holding. (Claims 26 and 27 recite species within that generic formula). The claim

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is also adequately enabled because the specification provides a description of how to determine whether specified candidate inhibitors within that scope will be useful; the generic formula provides a reasonably definite starting point from which to begin testing suitable candidate compounds.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (703) 308-4335. The examiner can normally be reached on Monday, Tuesday and Thursday from 9am to 5pm, and on Friday from 11am to 7pm. The examiner is off Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

Frederick Krass
Primary Examiner
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